January 10, 2022

The O.R. Company Pty Ltd
Amesha Silva
Quality Assurance & Regulatory Affairs Manager
1/32 Silkwood Place
Carrum Downs, Victoria 3201
Australia

Re: K212505
Trade/Device Name: DUMI ManipulatOR (DUMI-350A)
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: November 30, 2021
Received: December 7, 2021

Dear Amesha Silva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212505

Device Name
DUMI ManipulatOR (DUMI-350A)

Indications for Use *(Describe)*
The use of the DUMI ManipulatOR is indicated in diagnostic laparoscopy, mini laparotomy, fertility exams, and salpingoplastic procedures where manipulation of the uterus is required.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## DUMI ManipulatOR - 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

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| **Submitted by:** | The O R Company Pty Ltd<br>1/32 Silkwood Rise, Carrum Downs, VIC, 3201, Australia<br>Phone: +61 3 9413 5555<br>Fax: + 61 3 9413 5556 |
| **Contact Person:** | Name: Nicole Conway<br>Title: Quality Assurance & Regulatory Affairs Manager<br>Phone number: +61 3 9413 5555<br>Email: nicole@theorcompany.com |
| **Date Prepared:** | 06 January 2022 |
| **Device Trade Name:** | DUMI ManipulatOR (DUMI-350A) |
| **Common name:** | Uterine manipulator |
| **Classification name:** | Obstetric-gynecologic specialized manual instrument |
| **Regulation number:** | 884.4530 |
| **Product Code:** | LKF (Class II) - Cannula, Manipulator/Injector, Uterine |
| **Panel:** | Obstetrics/Gynecology |
| **Predicate Devices:** | Panpac Medical Corporation ---- Panpac Uterine Manipulator Injector, Model UMI 4.5 (K092980)<br>The predicate device has not been subjected to a recall. |
| **Device Description:** | The DUMI ManipulatOR is a sterile, single use, disposable medical device designed for the intra-operative manipulation of both the anteverted and retroverted uterus as well as facilitating simple and effective dye studies.<br>The device includes an anatomically designed balloon at the distal end that is injected with air by syringe through the luer connector of inflation valve. The three-way hub can accommodate fluid and can be used for dye studies. |
| **Indications for use:** | The use of the DUMI ManipulatOR is indicated in diagnostic laparoscopy, mini laparotomy, fertility exams, and salpingoplastic procedures where manipulation of the uterus is required. |
| **Substantial Equivalence Discussion:** | Indications:<br>The ORC DUMI ManipulatOR and UMI 4.5 have almost identical indications for use. Both devices are used for diagnostic procedures such as laparoscopy, minilaparotomy, fertility examinations and salpingoplastic procedures where manipulation of the uterus is required. There is no difference in intended use.<br><br>Technological characteristics:<br>Both the DUMI ManipulatOR and the UMI 4.5 share almost identical technological characteristics. The designs of both devices consist of a catheter, handle and a balloon to help with manipulation of tissue. The devices have the following differences:<br>• There is a 20mm difference in length between DUMI ManipulatOR and UMI 4.5.<br>• The shape of the DUMI ManipulatOR balloon is apple shaped while it is elongated for the predicate. They are the same volume (10cc)<br>• There are minor differences in handle design<br><br>The differences do not raise different questions of safety and effectiveness.<br><br>Performance:<br>As noted in the summary of testing below, the DUMI ManipulatOR was evaluated for performance and demonstrated to be as safe and effective as the predicate. |

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| **Summary of Testing/Data:** | The design of The OR Company's DUMI ManipulatOR device is based on Panpac Medical Corporation's Uterine Manipulator Injector (Model UMI 4.5) device. The DUMI ManipulatOR is demonstrated to be substantial equivalent to the Panpac Medical Corporation's Uterine Manipulator Injector (Model UMI 4.5) device.<br><br>A series of preclinical physical, mechanical and biocompatibility tests were performed to assess the safety and effectiveness of The O.R Company Pty Ltd's DUMI ManipulatOR as compared to the predicate.<br><br>The tests were conducted in accordance with relevant standards listed below and have successfully met predetermined acceptance criteria:<br>ISO 13485:2016 Medical devices Quality management systems Requirements for regulatory purposes<br>FDA 21 CFR 820 Quality System regulations<br>ISO 14971: 2019 Medical devices application of risk management to medical devices<br>ISO 11135:2014 Sterilization of health-care products-ETO Requirements for the development, validation & routine control of a sterilization process for medical device<br>ISO 11737-1: 2018 Sterilization of Medical devices-Microbiological methods-Part 1: Determination of a population of microorganisms on products<br>ISO 11737-2: 2019 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process<br>ISO 11607-1 : 2019 Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems<br>ISO 11607-2: 2019 Packaging for terminally sterilized medical devices Part 2: Validatio n requirements for forming, sealing and assembly processes<br>ASTM F88 /F88M-15 Standard test method for seal strength of flexible barrier materials.<br>ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration.<br>ASTM F2096-11 (2019) Standard Test Method For Detecting Gross Leaks In Packaging By Internal Pressurization (Bubble Test)<br>ISO 10993-1:2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process<br>ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity<br>ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization<br>ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity<br>EN 14372:2004 REACH Regulation (EC) No 1907/2006- Non-DEHP<br>ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices<br>ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems<br>ISO 2859-1:1999 Sampling procedures for inspection by attribute — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection<br>ASTM F3172-15 Design verification device size and sample selection for Endovascular devices<br>ISO 80369-7: 2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications<br><br>The specific tests undertaken included:<br>EO Sterilization:<br>• EO Sterilization Validation<br>• EO Residues<br>• Bacteriostasis and Fungistatis |

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| | • Bioburden<br>Shelf Life:<br>• Packaging integrity post 5 year accelerated aging<br>• Performance post 5 year accelerated aging<br>Packaging:<br>• Seal Strength of Flexible Barrier Materials<br>• Dye Penetration<br>• Sterility<br>Transportation:<br>• Handling<br>• Loose Load Vibration<br>• Low Pressure (High Alititude) Hazard<br>• Vehicle Vibration<br>• Handling<br>Biocompatibility:<br>Both devices are used in the same anatomical site and the same components of both devices come in short term contact with the mucosal membranes of the uterus and the vagina.<br>All patient contacting components of both devices have been tested for biocompatibility and have been found to be non-toxic, non-sensitizing, non-cytotoxic and non-irritating. The raw materials have all been used in various combinations by not only The O.R Company and predicate devices but also by uterine manipulators currently on the market. The materials are all well-characterized, are all commonly used in these and other medical devices. The following tests were conducted on the subject device:<br>• Cytotoxicity<br>• Sensitization<br>• Acute Systemic Toxicity<br>The performance tests listed below have demonstrated that The O.R Company Pty Ltd's DUMI ManipulatOR performs at least the same as the predicate device PanPac Medical Corporations UMI 4.5:<br>• Intrauterine balloon capacity and diameter test<br>• Intrauterine balloon fatigue test (repeat inflation)<br>• Intrauterine balloon burst test<br>• Air leakage test for prolonged time<br>• Spring load locking mechanism force test<br>• Component joint strength test<br>• Tip deflection test<br>• Balloon adhesion strength test<br>• Luer connector leakage test |
| **Conclusion:** | The subject device, DUMI ManipulatOR share similar indications and technological characteristics as the predicate device. All tests undertaken to demonstrate substantial equivalence of the DUMI ManipulatOR meet the requirements of its predetermined acceptance criteria. The test results confirm that the The O.R Company Pty Ltd's DUMI ManipulatOR is as safe and effective as the predicate device. Therefore, the DUMI ManipulatOR is substantially equivalent to the predicate. |

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